



Bay Area Dioxins Project

Frequently Asked Questions: Autoclaving an Acute Care Hospital's Regulated Medical Waste

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The San Francisco Bay Area municipalities participating in the Bay Area Dioxins Project are asking hospitals to rethink the way they manage their regulated medical waste because medical waste incineration is one of the nation's leading dioxins emissions sources. To assist hospitals with considering the viable alternatives for medical waste management, the Bay Area Dioxins Project has compiled a set of materials for your use, including this set of answers to common questions about autoclaving an acute care hospital's regulated medical waste

Why is autoclaving recommended? All regulated medical waste can't be autoclaved.

Most regulated medical waste can be treated effectively with an autoclave. Almost all California hospitals—including those with on-site autoclaves—send pathological, chemotherapy and pharmaceutical wastes off-site for incineration, which has until recently been the only legal option for these 3 waste streams. Because the law requires that these waste types be separately containerized and labeled, handling them differently than most regulated medical waste isn't a problem for most hospitals. Since incineration is polluting and expensive, minimizing these 3 waste streams is important—for example, as many pharmaceuticals as possible should be returned to manufacturers or sent to reverse distribution companies. DHS is reviewing alternative technologies for treating regulated medical waste types that currently require incineration. (Check the DHS Internet site www.dhs.ca.gov/medicalwaste for the latest information).

How do autoclaves effectively treat wastes that the steam doesn't touch?

Treatment is accomplished by the heat—not by contact with the steam. The heat from autoclaving (at least 250°F for at least 30 minutes) destroys the pathogens in the waste. Even though steam contact is not essential, the steam serves a critical role—to carry heat into the autoclave. Just like a pressure cooker, an autoclave uses elevated pressure to heat moisture-laden waste to above the boiling point of water (212°F). At atmospheric pressure, the temperature would stop rising until all water boils off.

Does autoclaving provide adequate treatment efficacy for all infectious agents?

Yes, for most of the regulated medical waste typically managed by acute care hospitals. Ordinary autoclaving is not approved for pathological, chemotherapy, and pharmaceutical wastes (see above). Wastes from certain infectious agents (e.g., prions like Creutzfeldt-Jakob disease [CJD]) always must be source-segregated and need special management. The Centers for Disease Control has guidelines for managing such wastes, which include special autoclave operating conditions as one treatment option.

What does an autoclave cost?

Cost depends on the autoclave size, and whether the autoclave has attachments, like a compactor or a grinder. A basic autoclave for a general acute care hospital should cost between \$100,000 and \$250,000 installed. Autoclaves with integrated grinders and compactors (capable of handling all of a hospital's solid waste) are somewhat more expensive. Typical equipment lifetime is 10 to 15 years.

Incineration renders waste unrecognizable— isn't that important for our liability?

No. California state law does not require that any medical waste be rendered unrecognizable. Facilities with autoclaves generally rely on the changed appearance of autoclave bags to provide their own staff, waste haulers, and landfills with a visual cue that formerly infectious waste has been properly treated. Autoclave bags are commonly designed to change during autoclaving (e.g., to shrink tightly or to highlight indicator tape), readily showing that autoclaving has been completed successfully.

Good communication with the hospital's waste hauler and landfill is always helpful—whether or not the hospital's waste includes waste rendered non-infectious by autoclaving. Questions about medical waste do occur at landfills, but when the landfill has been consulted about the autoclaved waste prior to its arrival, Bay Area hospitals and the local commercial autoclaving facility report that questions about autoclaved waste are very infrequent.

Grinders can be used in association with autoclaves to render autoclaved waste unrecognizable; however, grinders have important down sides. Added maintenance is required for their physical equipment, equipment failures can be hazardous to repair, and they create worker safety hazards, including possible air emissions of infectious agents when grinding occurs prior to autoclaving.

Won't it be a problem to ensure HIPAA compliance for certain items?

Regulated medical waste management is not an appropriate way to deal with Health Insurance Portability and Accountability Act (HIPAA) compliance. Proper HIPAA compliance involves obliterating names or removing labels from sample containers and other items prior to disposal. Even incineration cannot assure destruction of confidential materials disposed of with regulated medical waste (accidents and operating problems do occur that cause some materials to not be obliterated). Since landfills commonly bury autoclaved medical waste immediately upon receipt, incidents of improper disposal of confidential materials with medical waste carry few practical risks.

How does the medical waste management process relate to JCAHO requirements?

While there are no specific Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requirements for medical waste treatment, it is important that any hospital's efforts to comply with JCAHO include its medical waste management operations. For on-site autoclaving, compliance with California Medical Waste Management Act permitting and operations requirements should satisfy JCAHO. A shift to autoclaving waste can be a JCAHO Performance Improvement (PI) item in the environmental improvement category.

What are the worker health and safety issues?

For autoclaving, the primary worker health and safety issues are physical safety, potential exposure to infectious agents and improperly disposed hazardous or radioactive materials, possible heat stress, and noise exposure. Engineering controls and training are the most common methods to improve worker safety.

- Physical safety associated with waste handling—Moving and lifting waste always has the potential for worker injuries. Designing facilities to minimize the need for manually lifting and moving waste containers reduces the potential for injuries. Training—and avoiding work situations that reward unsafe behaviors—can further reduce risks.
- Potential for exposure to infectious agents—Unusual incidents, like spills of untreated waste or equipment failures, can expose workers to infectious materials. Good safety planning (including compliance with the Occupational Safety and Health Administration Bloodborne Pathogen Standard), proper protective equipment, and worker training can prevent worker exposures during such incidents.
- Potential for exposure to hazardous or radioactive materials—Properly segregated regulated medical waste does not contain hazardous or radioactive materials, but incidents of improper disposal do occur. Waste collection and waste treatment workers can be trained to identify visually potentially improperly disposed materials and to set aside red bags containing such materials for proper management. Commercial autoclave facilities use automated systems to measure radiation levels in each container, separating out contaminated wastes for proper management. Operating autoclaves in well-ventilated areas minimizes worker exposure.
- Heat stress—Hot weather—or indoor autoclave operation—can create uncomfortably hot working conditions. Ventilation, scheduling, and other measures should be implemented to avoid hot working conditions, as they often cause workers to avoid using personal protective equipment. When hot working conditions cannot be avoided, attention should be paid to ensure workers and supervisors follow heat stress precautions (e.g., water consumption, cooling breaks).
- Noise—Some autoclave equipment, particularly when operated indoors, may exceed safe noise exposure levels. In such cases, a hearing conservation program should be implemented.

Management oversight of on-site autoclaves can minimize worker safety risks by ensuring that employees have proper training for normal operations and for incidents like spills, and that staff follow operational procedures carefully.

What emissions does an autoclave have? Are they harmful?

Every medical waste treatment system releases pollutants to the environment—autoclaves are no exception. Autoclaves differ from most other medical waste treatment systems for two reasons:

- (1) New pollutants are not formed in the process (due to lower operating temperatures)
- (2) No toxic or reactive chemicals are used in the treatment process

This means that the pollutants released from autoclaving are the same ones that enter the autoclave in the medical waste. This is the fundamental reason why proper waste segregation—particularly to avoid placing hazardous or radioactive materials in red bags—is essential to safe autoclave operation.

Autoclaves can potentially have two types of harmful emissions: infectious agents and hazardous pollutants. If the autoclave is operating properly, infectious agents should not be released in quantities capable of causing infection (a 1993 study by Research Triangle Institute¹ validated this assumption). Accidents, improper infectious waste handling, or improper autoclave operation can release infectious agents into the environment (the same is true for any regulated medical waste treatment method). Medical Waste Management Act compliance requirements are designed to prevent releases of infectious agents. Compliance, together with good planning, training, and management oversight should minimize these risks.

Available data suggest that most hazardous pollutants released from autoclaves come from improperly disposed materials like laboratory solvents or mercury-containing equipment. Materials in ordinary regulated medical waste can, however, release embedded pollutants during autoclaving or when decomposing in a landfill. For example, some red bags contain cadmium, a toxic metal. Polyvinyl chloride (PVC) plastic contains plasticizers like diethylhexyl phthalate (DEHP), a reproductive toxicant that may adversely affect fish and other aquatic species. Hazardous pollutant releases from autoclaves are not generally regulated, primarily because regulatory agencies do not believe that the emissions are of great concern (however, air emissions have never been tested for hazardous pollutants).

Everything that enters an autoclave leaves in one of the three ways as described below.

- Wastewater (discharged to the sewer). During the autoclave cycle, steam extracts some substances from the waste. At the end of the cycle, these substances are discharged with the condensed steam into the sewer. Air emissions control devices using water sprays may also catch vaporized chemicals and wash them into the sewer. Wastewater treatment plants regulate discharges that may affect their operations or their compliance with limits on their discharges to rivers and bays. In general, small autoclaves like those in laboratories and hospitals do not have to obtain permits because wastewater treatment plants do not believe discharges are of concern. Larger facilities—like large regional off-site autoclaves—usually are closely regulated by wastewater agencies. Limited available data (from two large autoclaves) shows levels of metals and most priority pollutants (except solvents) to be well below local discharge limits. Solvents concentrations were occasionally high, suggesting a non-routine source, like improper disposal.
- Air Emissions. At the end of the autoclave cycle, the autoclave uses a vacuum to remove steam, which exits through a condenser. Uncondensed steam vapor—and possibly pollutants vaporized during the autoclave cycle—exit from the emissions vent (which sometimes contains a high-efficiency filter or a water spray scrubber). Opening the autoclave chamber releases additional vapor. Because they do not believe autoclave emissions carry significant quantities of pollutants, air quality agencies do not routinely oversee autoclave emissions, except to ensure that odorous emissions do not become a nuisance. Other than worker safety-oriented tests conducted at the request of the National Institute for Occupational Safety and Health (which did not show any worker safety standard exceedances),² no testing of hazardous pollutants in autoclave emissions has been reported.
- Landfill. Treated waste is usually sent to an ordinary solid waste landfill for disposal. While solid waste regulatory agencies and landfill operators seek to avoid disposal of hazardous pollutants in ordinary landfills, the practical barriers associated with testing garbage for hazards other than radiation offer limited means of keeping improperly disposed

¹ Research Triangle Institute (RTI), *Evaluation of Potential Biological Emission from Alternative Medical Waste Treatment Technologies*, Final Report, Prepared for USEPA Office of Solid Waste, July 1993. In the portion of the study that evaluated autoclaves, an on-site hospital and an off-site medical waste treatment autoclave were tested. RTI sampled air and fluids exhausted from the autoclaves before, during, and after treatment, as well as from the plume exiting the chamber as the door was opened. The waste was spiked with indicator organisms for the tests. For both autoclaves, no indicator organisms were recovered above background levels from any sampling/emissions point (even during pre-cycle evacuation).

² K. Owen, K. Leese, L. Hodson, R. Uhorchak, D. Greenwood and D. Van Osdell, Research Triangle Institute and Eugene Cole, DynCorp, *Control of Aerosol (Biological and Nonbiological) and Chemical Exposures and Safety Hazards in Medical Waste Treatment Facilities*, Final Report, Contract No. 200-95-2960; RTI Project 93U-6449, November 1997.

toxic pollutants out of landfills. In a landfill, waste may decompose to release hazardous pollutants to ground water and leachate.

Why emphasize waste reduction and proper segregation of waste?

Proper segregation is essential to safe operation of any regulated medical waste treatment system, whether it be an autoclave or an incinerator. Proper segregation cannot be overemphasized—it complies with the law, ensures JCAHO compliance, protects workers, and protects the environment. Effective hospital programs to promote proper regulated medical waste segregation have three benefits:

- Reducing regulated medical waste volume, thus reducing costs for regulated medical waste management
- Preventing unsafe and illegal disposal of hazardous or radioactive materials with regulated medical waste
- Greatly reducing segregation violations (improper disposal of regulated medical waste)

Reducing regulated medical waste doesn't just reduce disposal costs—it also reduces the size of treatment systems and facilities to manage it.

Waste isn't just trash—it is wasted resources; it is pollution. Implementing pollution prevention, recycling, and improved segregation programs can have a substantial financial impact for a hospital, while making a meaningful community contribution. See the Fact Sheet "Resources for Health Care Pollution Prevention" for more information.

Isn't Medical Waste Management Act permitting a headache?

No. Most acute care hospitals only need to do some basic paperwork to obtain a Medical Waste Treatment permit from the local California Medical Waste Management Act Enforcement Agency. The permit is issued by the same agency that administers medical waste generator requirements (California DHS has a handy list of contacts on its Internet site www.dhs.ca.gov/medicalwaste). Depending on the physical modifications needed to accommodate the autoclave, hospitals may need a local building permit or Office of Statewide Health and Planning Development (OSHPD) review (see below for more information about OSHPD). See "Permit Requirements for Installing Autoclaves at Acute Care Hospitals" more information.

Is OSHPD review required?

Probably, but the approval would almost certainly fall under the Office of Statewide Health and Planning Development's (OSHPD's) expedited review process because autoclave installation is a relatively small equipment installation project. If a hospital seeks the OSHPD expedited review at the same time it submits its Medical Waste Management Act permit application, OSHPD review should not delay autoclave installation.

The Office of Statewide Health and Planning Development (OSHPD) must approve several types of facility changes that are normally associated with autoclave installation:

- Utility use changes,
- New utility lines,
- Building exterior modifications, and
- Structural adequacy of the anchorage to the building (for indoor installations).

Installations involving none of these activities may be exempt. Any decision to skip OSHPD review should be thoroughly checked, as there are penalties for non-compliance.

The primary work associated with the OSHPD review will be to prepare carefully detailed plan drawings in the format required by OSHPD. When submitting the plans, expedited review should be specifically requested. The OSHPD FREER Manual describes expedited review process (www.oshpd.cahwnet.gov/fdd/about_us/organization/CAS/1997-Freer.PDF).

Strategies are available to simplify OSHPD review:

- If an autoclave were installed in or adjacent to a "non-OSHPD" building, local building permit requirements would apply, but OSHPD review could be avoided. This is an option for hospitals that have campus structures not attached to the main hospital building that are not included in a campus-wide OSHPD permit. While using an out-building for waste management could have advantages, the possible negative consequences should also be considered. For example, moving regulated medical waste from a main hospital building to an out-building adds a risk of uncontrolled spills and may contribute to worker injuries associated with the extra physical handling of the waste.

- For very simply installations (where only utility use changes are required), it may be possible to use OSHPD's field approval process, where the OSHPD area compliance officer approves the plans during a facility visit.
- For interior projects requiring structural review of the anchorage to the building, using pre-approved drawings greatly speeds project review. With pre-approved drawings, the structural review may not need to be included in the OSHPD review of a specific autoclave installation. Since the one-time pre-approval can be initiated at any time, seeking it early—before the hospital starts its Medical Waste Management Act and OSHPD permit applications—will save time for current and future equipment installations.

How does medical waste management relate to Seismic Safety Act compliance?

To comply with the California Seismic Safety Act (SB 1953), many California hospitals are planning to remodel or reconstruct facilities in by 2008. Hospital remodeling or reconstruction is the perfect time to improve designs for medical waste management. Designs can provide for future waste management activities—like a location suitable for an autoclave and places for storing materials awaiting off-site recycling. In hospital patient care areas, designs can allow for proper container placement to facilitate proper segregation of regulated medical waste and recycling. Designing a mercury-free hospital eliminates possible improper mercury disposal.

What else can hospitals do to reduce dioxins?

The Bay Area Dioxins Project has resources for institutions seeking to prevent dioxins releases as a direct or indirect consequence of operations. Some good options for hospitals include:

- Replacing diesel with cleaner fuels—The Bay Area Air Quality Management District says that diesel engine emissions are one of the two top dioxins emissions sources in the San Francisco Bay Area. Diesel burning creates many other pollutants—like fine particulate matter, nitrogen oxides, and polyaromatic hydrocarbons—that are known problems for public health. Replacing diesel-powered equipment, vehicles, and back-up generators with natural gas, electric, or biodiesel alternatives reduces pollution. Hospitals may be able to partner with local governments to obtain grant funding for the incremental cost of diesel substitutes (learn more about this option from a memorandum available on the Internet at http://dioxin.abag.ca.gov/project_materials.htm#diesel).
- Purchasing chlorine-free paper—Paper bleaching without chlorine avoids creating dioxins and other toxic chlorinated organic chemicals. Since chlorine-free paper with high recycled content is available, hospitals can close the loop with their own recycling programs. Information on products, pricing, and practicalities of making the chlorine-free paper transition is available from the Bay Area Dioxins Project (http://dioxin.abag.ca.gov/project_materials.htm#paper).
- Making your next building or remodeling project a green building project—Green buildings are not only better for the environment—they are safer and more pleasant for workers and patients. Green building information for hospitals is available from the Healthy Building Network (www.healthybuilding.net). The Bay Area Dioxins Project has compiled alternatives to PVC building products (http://dioxin.abag.ca.gov/project_materials.htm#building_materials).

What is the Bay Area Dioxins Project?

In 1999 and 2000, several San Francisco Bay Area municipalities and the Executive Board of the Association of Bay Area Governments (ABAG) adopted resolutions calling for dioxins pollution prevention and dioxins elimination. The resolutions were motivated by concerns about the health and environmental effects of typical dioxins exposures as well as by the additional risks experienced by highly exposed communities (e.g., members of communities who routinely consume fish from San Francisco Bay and neighbors of a regional medical waste incinerator). To meet the challenge of the resolutions—the elimination of dioxins formation—the municipalities initiated the San Francisco Bay Area Dioxins Project under the auspices of ABAG.

The primary goals of the Bay Area Dioxins Project are:

- To pool local governments' knowledge and resources to study dioxins and to provide information about possible solutions or actions for local governments in the San Francisco Bay Area;
- To coordinate efforts with state, federal, and regional agencies working on dioxins issues; and
- To work with community groups, trade and industry groups, and the general public on issues of concern related to dioxins.

More information about the project is available on the Internet at <http://dioxin.abag.ca.gov/>